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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/681,740

10/09/2003

Ronald D. Berger

2784-36

8147

23117

7590

08/22/2008

NIXON & VANDERHYE, PC

901 NORTH GLEBE ROAD, 11TH FLOOR

ARLINGTON, VA 22203

EXAMINER

GETZOW, SCOTT M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

08/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/681,740

Applicant(s)

BERGER, RONALD D.

Examiner

/Scott M. Getzow/

Art Unit

3762

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

Claim Rejections - 35 USC § 103

1. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smits (4,641,656) in view of Alferness et al (6,169,922).

Smits teaches a ICD which has electrodes inside the heart, as well as electrodes on the surface of the heart. The electrodes on the heart are connected in common, thus resulting in effectively a single electrode. Also, the electrodes inside the heart are connected in common, resulting in effectively a single electrode, see figure 24-27, and columns 17-20. Column 18:48 also states that the device of Smits provides a system which stimulates a majority of the mass of the heart. Alferness, as stated in the previous office action, teaches stimulation through the heart via two electrodes which are part of a 'cage' or wrap. It would have been obvious to use the wrap of Alferness with the device of Smits since such would be a simple substitution of known elements yielding a predictable result. That is, the epicardial electrodes of Alferness would replace the epicardial electrodes of Smits, and operationally would be the same polarity as taught in Smits. Further, it would also have been obvious to use the wrap of Alferness with the device of Smits so that the heart could be restrained from overexpansion, as taught in Alferness. That is, the electrodes 252,254 of Smits could be integrated in the wrap of Alferness, and replace the electrodes of Alferness, so that the patient could get the benefit of whole heart defibrillation as well as the restraint given by the use of the wrap. Re claim 13, the current density can be adjusted by making the electrodes larger or smaller, or closer or farther apart; depending upon what is desired by the physician based on patient results to treatment. Further, the

amplitude of stimulation can be adjusted, as is known in the art, from low to high depending on what works for the patient.

2. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman et al (4,030,509) in view of Alferness et al (6,169,922).

Heilman teaches an ICD which includes an electrode inside the heart as well as an electrode on the surface of the heart, where a shock is applied between them, as shown in figure 4. It would have been obvious to use the wrap of Alferness with the device of Heilman so that the restraint of overexpansion of the heart can be achieved as well as defibrillation. Further, Heilman, in other embodiments, teaches the use of more than one electrode placed on the surface of the heart.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Scott M. Getzow/ whose telephone number is (571) 272-4946. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott M. Getzow/
Primary Examiner
Art Unit 3762

SMG